Can Data from Programs for the Prevention of Mother-to-Child Transmission of HIV be Used for HIV Surveillance in Kenya?

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SYNOPSIS

Objective. In Africa, HIV surveillance is conducted among antenatal clinic (ANC) attendees using unlinked-anonymous testing (UAT). In Kenya, the utility of prevention of mother-to-child transmission (PMTCT) program data for HIV surveillance was evaluated.

Methods. UAT and PMTCT data were compared at the same clinics and for the same time (2003 UAT survey) period. The HIV testing uptake for PMTCT was defined as the number of ANC attendees tested for HIV out of those who had their first ANC visit during the ANC surveillance period. Odds ratios and 95% confidence intervals were calculated to determine associations between demographic characteristics and HIV testing acceptance.

Results. Of 39 ANC-UAT sites, six had PMTCT data. PMTCT data were recorded across several logbooks with varying quality. For PMTCT, 2,239 women were offered HIV testing and 1,258 (56%) accepted; for UAT, 1,852 women were sampled. Median UAT-based HIV prevalence was 12.8% (range, 8.1%–26.3%) compared with 14.4% (range, 7.0%–27.2%) in PMTCT. HIV testing acceptance for PMTCT ranged from 48% to 69% across clinics, and was more likely among primigravidae than multigravidae.

Conclusion. Because of varying PMTCT data quality and varying HIV testing acceptance for PMTCT, PMTCT-based HIV prevalence estimates cannot currently replace UAT-based estimates in Kenya.

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Accurate estimates of the numbers of individuals living with HIV infection are essential for the planning and monitoring of HIV prevention and care programs. In countries with generalized HIV epidemics, where the prevalence of HIV is consistently >1% in the general adult population, these estimates are obtained primarily from data collected from antenatal (ANC) clinic sentinel surveys.[1,2] These surveys are often the only reliable data source to estimate HIV prevalence in the general adult population.[3] The surveys are conducted at regular intervals, usually annually, at selected clinics called sentinel sites, where left-over blood drawn for syphilis serology is tested for HIV antibodies. Since this testing is unlinked (the link between the specimen and the personal identifying information, such as the medical record number or patient name, is removed prior to HIV testing) and anonymous (the health staff cannot identify an individual's test result), the women cannot be informed of their HIV test results.

Surveillance experts have explored whether other data sources could be used to obtain reliable national estimates of HIV prevalence because ANC sentinel surveys require significant resources and because the HIV test results cannot be returned.[4] One option is to use results of HIV tests conducted as part of prevention of mother-to-child transmission (PMTCT) programs. The accessibility of these programs, where HIV testing is voluntary and linked to therapy to prevent transmission of HIV from pregnant women to their infants, is increasing rapidly and will soon provide HIV testing data on many more ANC attendees than through serosurveys. For example, in 2004 an estimated 5%–10% of pregnant women were offered such services in Africa. However, because pregnant women can refuse HIV testing for PMTCT, PMTCT-based HIV estimates may be biased and the magnitude and direction of this bias is unknown.[4] We conducted a study to assess the accessibility and quality of PMTCT program data, to compare HIV prevalence estimates from PMTCT programs with those from ANC sentinel surveillance, and to identify determinants of differences in HIV prevalence estimates.

METHODS

Background

Kenya is a country with a generalized HIV epidemic. In 2003, the HIV prevalence among ANC attendees at 39 sites was estimated at 9.4%. With increased funding and strong political will, the Ministry of Health initiated a rapid expansion of PMTCT services in ANC clinics, from fewer than ten sites in 2001 to 214 sites in 2004. This expansion provided an opportunity to conduct our study in Kenya at sentinel sites that provided PMTCT services.

The Kenyan ANC-based HIV sentinel surveillance is conducted through annual surveys, currently in 39 sites. During a three-month period, leftover blood from routine syphilis screenings of ANC attendees at their first visit is collected for HIV surveillance. Routinely recorded demographic information is transcribed from a laboratory request form onto the surveillance data collection form. In the 2003 serosurvey, 12,616 specimens were collected. Following the Joint United Nations Programme on HIV/AIDS (UNAIDS)/World Health Organization (WHO) guidelines,[2] the leftover blood is collected using an unlinked anonymous testing (UAT) strategy, whereby the specimen is labeled with a code and the linkage between personal identifiers and the specimen is removed prior to HIV testing. In 2003, HIV testing for surveillance was conducted at the facility laboratory and consisted of a single rapid test, the Determine® HIV-1/2 test (Abbott Laboratories). Transcribed data included age, marital status, education, urban/rural residence, number of abortions, number of live births, and syphilis test result. These individual-level data are sent to the National AIDS and STD Control Program (NASCOP) to analyze HIV trends throughout the country. National HIV prevalence estimates are obtained after adjusting for urban/rural residence and for the estimated female to male ratio in HIV prevalence, using standardized procedures developed by UNAIDS.[1] National epidemiological reports are produced describing HIV prevalence by various demographic characteristics.[5]

In antenatal clinics with PMTCT services, HIV testing for PMTCT is based on counseling and testing with consent, using an opt-in or opt-out strategy. In an opt-in strategy, the pregnant woman can actively choose whether to be tested for HIV after individual pre-test counseling. Opt-out strategy is the routine non-compulsory approach to prenatal HIV testing. Health staff hold group education sessions during which pregnant women are informed that they will be routinely screened for HIV and other diseases, and that they have the right to refuse testing. Women may accept HIV testing for PMTCT at any visit or refuse testing. For those who accept HIV testing, a blood sample is collected with personal identifiers. All sera are tested at the facility laboratory with two rapid tests: Determine® HIV-1/2 and UniGold® HIV-1/2 (Trinity Biotech). If these two tests yield discordant results, an enzyme immunosorbent assay (EIA) or InstantScreen® rapid HIV-1/2 (Gaifar GmbH) test is conducted to determine the final HIV test result. PMTCT services report summary (or aggregated) PMTCT data quarterly to

NASCOP, including the proportion of ANC attendees tested for HIV and the HIV prevalence among those tested. Individual patient data, including age, gravidity, parity, and HIV and syphilis test results for each ANC attendee participating in the PMTCT program are recorded in logbooks that remain at the clinic.

Site selection, data collection and entry

Of 39 ANC clinics used as sentinel sites for surveillance, 13 had PMTCT data in 2003 but seven had started PMTCT programs after the 2003 ANC surveillance sampling period (May to August 2003). For this study, the six ANC clinics that had PMTCT data during the 2003 ANC surveillance sampling period were selected, namely, Mbale, Tiwi, Busia, Nakuru, Chulaimbo, and Kisumu. These sites were located in four of the eight Kenyan provinces; three sites (Busia, Nakuru, Kisumu) were urban, two (Mbale, Chulaimbo) were rural, and one (Tiwi) was "mixed," with a population consisting of both urban and rural residents. The 2003 ANC surveillance data (electronic database) and aggregated PMTCT program data were provided by NASCOP. Since individual-level PMTCT data were not routinely reported to the national level, they had to be collected at each of the six selected clinics. These individual-level PMTCT data were typically recorded across two to three logbooks: the general ANC logbook that included all women attending the antenatal clinic, the PMTCT counseling logbook that included women who accepted HIV testing, and the ANC laboratory logbook that recorded HIV test results. These data were captured by digital photography of the logbooks after all patient names were covered to protect confidentiality. For each site, PMTCT data collection was restricted to the ANC surveillance sampling period. Therefore, most ANC attendees were included in both the PMTCT and ANC surveillance data sets. Individual PMTCT data were entered into Epi Info[6] from digital pictures of logbooks for all ANC attendees who came for their first ANC visit during the ANC surveillance sampling period. To assure comparability of HIV testing strategy for this study, only the Determine® HIV-1/2 test result was used from the PMTCT data. The criteria used to assess the availability and quality of PMTCT program data were their accessibility at national level and/or at clinic level, the accuracy and consistency of data collection, and the ease of entering data into an electronic database.

Statistical analysis

Data from ANC surveillance had been previously analyzed by NASCOP. In the PMTCT data, we defined the HIV testing uptake for PMTCT as the number of ANC attendees tested for HIV out of those who had their first ANC visit during the ANC surveillance period. We calculated odds ratios (OR) and 95% confidence intervals (CI) to determine associations between demographic characteristics and HIV testing acceptance. Factors associated with HIV testing acceptance in which the 95% CI did not overlap one in the univariate analysis were entered into logistic regression models in SAS,[7] including the four sites that had data on gravidity, looking at sites separately and combined.

Since most ANC attendees were present in both the PMTCT and ANC surveillance groups, we considered them as dependent samples. Therefore, statistical tests for the comparison of ANC surveillance-based and PMTCT-based HIV prevalence could not be conducted and only the descriptive results are presented. We analyzed the data by site and calculated the median site HIV prevalence and ranges for the six selected sites.

RESULTS

During the 2003 ANC surveillance sampling period at the six selected clinics, 2,239 women were offered HIV testing for PMTCT and 1,258 (56%) accepted; for ANC surveillance, 1,852 women were recruited and tested for syphilis and HIV (Figure).

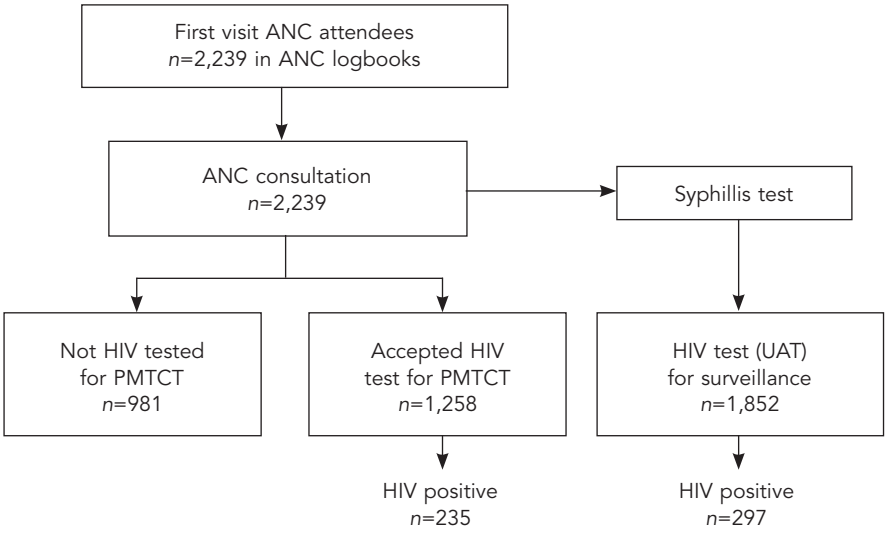
Availability and quality of PMTCT data

Access to general ANC logbooks, PMTCT counseling logbooks and ANC laboratory logbooks was limited since they were being used by ANC staff. Data could be entered electronically only by taking digital photographs of the logbooks. Data varied in quality (handwriting was not always clear) and the logbook format was not uniform across sites. The number, type, and order of variables recorded in the same logbooks varied by site and over time within the same site. For example, gravidity data were missing at Chulaimbo and Mbale clinics. Because of the lack of logbook standardization, data could not simply be entered electronically.

HIV testing uptake for PMTCT

The proportion of women accepting HIV testing for PMTCT was 69% in Chulaimbo, 68% in Kisumu, 51% in Tiwi and in Busia, 49% in Mbale, and 48% in Nakuru. The median HIV testing uptake for the six sites was 51%. In univariate analysis, the likelihood of accepting HIV testing for PMTCT was greater among women aged <25 years than among women aged 25 years and older (58.6% vs. 52.2%; crude OR=1.3; 95% CI 1.1, 1.5) (Table 1). The acceptance of HIV testing was also more likely among primigravidae than among multigravidae (71.5% vs.63.4%; OR=1.4; 95%

Figure. ANC attendees in PMTCT and ANC surveillance data at six sites



ANC = antenatal clinic

PMTCT = prevention of mother-to-child transmisson program

UAT = unlinked anonymous testing

CI 1.1, 1.8) and more likely among women attending Kisumu clinic than among those attending the other clinics combined (68.0% vs. 49.8%; OR=2.1; 95% CI 1.7, 2.7). After controlling for age, gravidity, and site using a logistic regression model, the association between gravidity and HIV testing acceptance increased (adjusted OR [AOR]=2.8; 95% CI 2.2, 3.5) and women attending Kisumu ANC clinic were still more likely to accept HIV testing for PMTCT compared with those attending any other site (AOR=2.1; 95% CI 1.7, 2.7), while age was no longer a predictor (Table 1) of HIV testing acceptance.

We assessed the variables associated with HIV testing acceptance for PMTCT by site. Although younger women (<25 years) accepted HIV testing more often than older women in four of six sites, in each site this difference was not statistically significant. Primigravidae accepted HIV testing more often than multigravidae

Table 1. Factors associated with HIV testing acceptance at the four sites with data on gravidity, based on PMTCT program data, Kenya May–August 2003[a]

	Received HIV test	*Crude OR*	*95% CI*	*Adjusted OR*	*95% CI*
Age					
12–24 years	58.6	1.3	1.1, 1.5	0.9	0.8, 1.2
25–45 years	52.2	Referent			
Gravidity					
1 pregnancy	71.5	1.4	1.1, 1.8	2.8	2.2, 3.5
≥ 2 pregnancies	63.4	Referent			
Site					
Kisumu	68.0	2.1	1.7, 2.7	2.1	1.7, 2.7
Other sites	49.8	Referent			

[a]Logistic regression controlling for age, gravidity, and site; including interaction term for gravidity and site

OR = odds ratio

CI = confidence interval

PMTCT = prevention of mother-to-child transmisson

in two of the four sites for which we had data on gravidity. This association was statistically significant for one site only (Tiwi health center, primigravidae HIV testing uptake=63% vs. multigravidae HIV testing uptake=45%; OR=2.1; 95% CI 1.2, 3.9).

HIV prevalence in ANC surveillance and in PMTCT program data sets

In the ANC UAT-based surveillance data, the median HIV prevalence in the six sites was 12.8% (range=8.1%–26.3%). In the PMTCT data, the HIV prevalence was 14.4% (range=7.0%–27.2%) (Table 2). In the ANC UAT-based surveillance data, the median HIV prevalence was 11.8% for women younger than 25 years (range=5.8%–22.9%). In the PMTCT data, the median HIV prevalence was 12.8% for women of this same age group (range=6.1%–23.9%), which was higher than the median ANC UAT-based HIV prevalence.

When HIV prevalence was examined by site, we found that in the ANC UAT-based surveillance data the HIV prevalence was lower than the prevalence from the PMTCT data in five of the six sites. The relative difference in HIV prevalence between the ANC UAT-based surveillance data and the PMTCT data ranged from –30% in Tiwi to +38% in Mbale, but the 95% confidence intervals between ANC UAT-based surveillance and PMTCT data overlapped for all sites (Table 2).

To assess if the difference in HIV prevalence in ANC surveillance data and PMTCT data was smaller when the HIV testing uptake was greater, sites were grouped by HIV testing uptake. At the sites with an HIV testing uptake ≥60%, the difference between ANC surveillance and PMTCT-based HIV prevalence was similar to that at sites with a HIV testing uptake ≤60% (data not shown).

DISCUSSION

For PMTCT data to be useful for surveillance, the data must be consistently and accurately collected, easily accessible, and provide either unbiased HIV prevalence estimates or have a consistent and measurable bias. In this Kenyan study, these conditions were not met. First, it was difficult to use PMTCT data because of varying data quality, data recording across several logbooks, and the fact that individual-level PMTCT data (e.g., logbooks) remained at the clinics. Second, HIV testing uptake for PMTCT was too low to make PMTCT data representative of all ANC attendees and was higher among primigravidae and among women attending a specific clinic. Finally, there was considerable inter-clinic variability in the difference between HIV prevalence estimates from PMTCT and from ANC surveillance data.

Aggregate PMTCT program data obtained at the

Table 2. ANC UAT-based HIV prevalence and PMTCT-based HIV prevalence by age group and ANC clinic, Kenya, May–August 2003

	ANC surveillance		*PMTCT*		
	n	*HIV prevalence (range)*	n	*HIV prevalence (range)*	
Median: all ages		12.8 (8.1, 26.3)		14.4 (7.0, 27.2)	
Median: 12–24 years	1,148	11.8 (5.8, 22.9)	831	12.8 (6.1, 23.9)	
Median: 25–49 years	701	17.3 (6.6, 34.2)	391	17.3 (8.7, 37.1)	
	n	*HIV prevalence (95% CI)*	n	*HIV prevalence (95% CI)*	*Received HIV test (percent)*
Clinic					
Mbale	172	8.1 (4.5, 13.3)	135	11.1 (6.4, 17.7)	48.9
Tiwi	283	9.5 (6.4, 13.6)	128	7.0 (3.3, 12.9)	51.0
Nakuru	399	9.8 (7.0, 13.1)	215	11.2 (7.3, 16.2)	47.9
Busia	298	15.8 (11.8, 20.4)	246	17.5 (13.9, 22.8)	50.9
Chulaimbo	300	21.7 (17.1, 26.8)	228	27.2 (21.5, 33.5)	69.1
Kisumu	400	26.3 (22.0, 30.9)	306	26.8 (21.9, 32.1)	68.0

ANC = antenatal clinic

UAT = unlinked anonymous testing

PMTCT = prevention of mother-to-child transmisson program

CI = confidence interval

national level were minimally useful for surveillance purposes because they provided HIV prevalence by clinic, but this prevalence could not be analyzed by age or by gravidity. Only line-listed data on individuals allow stratified analysis by demographic characteristics such as HIV prevalence in younger age groups, which is an important indicator for new infections.

The higher the proportion of women accepting HIV testing for PMTCT, the more representative will be the HIV prevalence of the ANC population. Unfortunately, in our study only slightly more than half of ANC attendees accepted HIV testing for PMTCT. Gravidity was a major factor influencing HIV testing uptake for PMTCT, with women having their first child being more likely to accept HIV testing. A study conducted in London in 2002[8] had similar findings. It is possible that primigravidae were more willing to accept any intervention proposed for their pregnancy, including screening for HIV, or that some multigravidae, may have been tested for HIV during a former pregnancy and did not feel the need for re-testing. HIV testing acceptance varied considerably by clinic, but we were not able to fully assess the factors influencing the clinic variability of HIV testing acceptance. Other studies have shown that service-related factors, including the use of an "opt-in" strategy (individual pre-test counseling with patients actively choosing whether to be tested) or an "opt-out" strategy (HIV testing routine, noncompulsory), the organization of services, human resources training, staff attitude, and availability of anti-retroviral medication at each facility may have a strong influence on HIV testing uptake. The opt-out strategy, for example, has proven to result in a better HIV testing uptake than the opt-in strategy.[9,10] Recently, a study conducted in Uganda[11] showed that the lack of antiretroviral drugs was a barrier to participation in PMTCT. In our study, the Kisumu clinic, which had one of the highest HIV testing uptakes, increased its HIV test acceptance rate significantly with a switch from an opt-in to an opt-out approach in 2002. Its PMTCT program also receives substantial technical and financial support from a foreign public health organization, resulting in better training and resources than some other clinics. In any case, in Kenya, uptake of HIV testing for PMTCT must be significantly higher for PMTCT data to be useful for surveillance.

Our study found no correlation between the level of HIV testing uptake and the difference between ANC surveillance and PMTCT-based HIV prevalence estimates. However, both the site sample sizes and the variability in HIV testing uptake across sites were relatively small (range=49%–69%). A wider range of HIV testing uptake, especially uptake below 30% and above 90%, may have given different results. Data from other countries can provide some insight as to how HIV testing uptake may influence the utility of PMTCT data for surveillance. In 2003, Thailand replaced UAT serosurveys with a system of annually collecting individual PMTCT program data over a one-month period. Although the overall HIV prevalence in Thailand is low (1.8%), 97% of ANC attendees accept HIV testing for PMTCT. Therefore, differences between PMTCT-based HIV prevalence rates and those obtained through ANC serosurveys should be negligible.[12] In Botswana, where HIV prevalence was high (38%) and HIV testing uptake for PMTCT was only 42% at the time, the PMTCT-based HIV prevalence estimates were similar to those derived from the UAT survey and therefore seemed to be a good proxy for UAT-based HIV prevalence estimates. In high HIV prevalence settings, biased PMTCT-based HIV prevalence estimates due to test refusals may be less likely than in epidemics with lower HIV prevalence.[13] A study conducted in one Ugandan hospital compared the HIV prevalence among ANC attendees who accepted HIV testing for PMTCT and among those who refused testing for PMTCT but were tested anonymously.[14] This study found that HIV prevalence was higher in PMTCT acceptors than in PMTCT refusers in months with HIV testing uptake $<70\%$, but similar in months with HIV testing uptake $\geq 70\%$. In this Ugandan study, PMTCT acceptors become more representative of the general population of ANC attendees when HIV testing uptake is $\geq 70\%$. These variations by country show that there is probably no direct correlation between the level of HIV testing uptake and the difference between ANC surveillance and PMTCT-based HIV prevalence estimates.

Our study did find important clinic variations in the difference in HIV prevalence estimates from PMTCT and from ANC surveillance data, even for similar levels of HIV testing uptake. These variations support the idea that for a given HIV testing uptake, the direction and magnitude of the selection bias introduced by voluntary testing may vary depending on patient and service-related factors, especially when a nonstandardized approach is used. The number of variables recorded in PMTCT services was limited and not consistent across sites, thereby preventing an assessment of the influence of factors such as marital status and education on test acceptance. ANC surveillance and PMTCT groups were not 100% identical. There were 17% more ANC attendees in the PMTCT data than in the ANC surveillance data, suggesting that: (*1*) reported ANC surveillance sampling dates may not have been completely accurate, (*2*) sampling for ANC surveillance may not have been 100% consecutive

because some women may not have been tested for syphilis, (*3*) some women may have been ineligible for sentinel surveillance (referrals from other hospitals), or (*4*) some women may have been recorded twice in the PMTCT logbooks. Finally, in our study, we were not able to compare HIV prevalence estimates among ANC attendees who refused HIV testing for PMTCT to HIV prevalence estimates of those who accepted testing.

ANC-UAT-based HIV surveillance data are known to have their own bias. In general, HIV prevalence from these surveys overestimates HIV prevalence among younger women (<20 years of age), as these sexually active young women do not reflect most young women. HIV prevalence from these surveys underestimates HIV prevalence in older women (>40 years of age), as HIV infection decreases fertility.[3] In addition, most ANC clinics selected for these surveys are in urban centers with higher HIV prevalence than in the country as a whole. However, ANC-UAT-based HIV surveillance is the best method currently in place to analyze HIV trends over time, but other methods such as population-based surveys with HIV testing can be added to national surveillance systems and used to adjust national HIV prevalence estimates. PMTCT-based HIV prevalence data likely inherit the limitations of ANC-UAT-based HIV surveillance. In contrast to PMTCT, ANC-UAT-based surveillance usually benefits from the special efforts made for data collection during the short surveillance period, including training, supervision, and highly standardized procedures.

In conclusion, data from PMTCT programs in Kenya have the potential to complement but not to replace ANC UAT-based HIV surveillance data. HIV prevalence data from PMTCT programs will soon be available in many more ANC clinics than those that participate in UAT surveys. These data can complement ANC-UAT-based HIV surveillance data by providing some information on geographic areas that do not participate in UAT surveys, but shouldn't be used to calculate estimated number of persons with HIV on those areas at this time. PMTCT data cannot currently replace ANC-UAT-based HIV surveillance data because PMTCT data lack consistent quality; PMTCT-based HIV prevalence estimates may differ from ANC surveillance-based estimates and possibly overestimate HIV prevalence due to low HIV testing uptake for PMTCT and selection biases in test acceptance. In order to obtain more representative HIV prevalence estimates, HIV testing uptake for PMTCT would have to be improved, with particular attention to multigravidae. Individual PMTCT data quality would also have to be improved by standardization of logbook format and by supervision of ANC staff to assure accuracy of data collection. Before ANC surveillance data can be replaced by PMTCT data for surveillance in Kenya, it will be important for PMTCT services to be available in a sufficient number of rural clinics to allow a good representation of rural areas. It will also be important for PMTCT services to be offered in the same 39 sentinel sites already conducting surveillance to allow trend analysis over time. Finally, the HIV testing algorithm used for PMTCT differs from that used for surveillance. Adjustments will need to be made to continue to assess trends overtime (e.g., using just the results of the first HIV test from PMTCT data, as we did for this analysis).

As a result of this study, the Kenyan sentinel surveillance protocol was revised in 2004 to include information on HIV testing acceptance for PMTCT for each ANC attendee sampled. This will allow for the direct comparison of HIV prevalence in women who accepted and refused PMTCT-related HIV testing during the surveillance period. Changes over time in HIV testing uptake and in PMTCT-based HIV prevalence within the same site will be monitored for program evaluation purposes. Once Kenya has PMTCT-based prevalence data available for five years or longer, modeled prevalence curves that are based on PMTCT data can be compared to those provided for the current estimates, based on ANC surveillance data. Because the results of our study may be country-specific, such comparisons need to be conducted in other countries. Similar studies are currently being conducted in Ivory Coast and Uganda.

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